

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparision the effect of intranasal ketamine hydrochloride and intravenous morphine sulfate on pain severity of patients with limb fracture

#### Protocol summary

##### Summary

Objective: assessment the effect of intranasal ketamine hydrochloride and intravenous morphine sulfate on pain severity of patients with upper or lower limbs fracture. Design: clinical trial without blinding Randomization: patients will allocate to two equal groups of intranasal ketamine hydrochloride and intravenous morphine sulfate according to table of random numbers. Participants including major eligibility criteria: this study will conduct on 104 patients with trauma in Ahvaz Imam Khomaieni and Gholestan hospitals. Main inclusion criteria include age range of 15 to 64 years and having upper and lower limbs fracture, and main exclusion criteria include low of consciousness; hemodynamic instability; addiction to drugs or opioids; mental retardation and psychosis; chronic cardiovascular diseases; being pregnant and breastfeeding; intranasal ketamine hydrochloride and intravenous morphine sulfate contraindication. Intervention: patients in intranasal ketamine hydrochloride group will receive 1 mg/kg ketamine hydrochloride of 10 ml solution (which put in sterile nasal drop bottle) via inhalation. Patients in intravenous morphine sulfate group will receive 0.1 mg/kg morphine sulfate via intravenous. Main outcome measures (variables): pain severity Setting and conduct: pain severity will assess in 0, 5, 10, 15, 20, 25, and 30 minutes in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016031027007N1**  
Registration date: **2016-05-28, 1395/03/08**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-05-28, 1395/03/08

##### Registrant information

###### Name

Somayyeh Gharibi

###### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 613333333

###### Email address

gharibi.s@ajums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Ahvaz Judishapur University of Medical Sciences

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-03-21, 1396/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparision the effect of intranasal ketamine hydrochloride and intravenous morphine sulfate on pain severity of patients with limb fracture

##### Public title

Comparison the effect of intranasal ketamine

hydrochloride and intravenous morphine sulfate on pain severity of patients with upper or lower limbs fracture

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: age range of 15 to 64 years; having upper and lower limbs fracture. Exclusion criteria: low of consciousness; hemodynamic instability; addiction to drugs or opioids; mental retardation and psychosis; chronic cardiovascular diseases; being pregnant and breastfeeding; intranasal ketamine hydrochloride and intravenous morphine sulfate contraindication.

## Age

From **15 years** old to **64 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **104**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

-

#### Secondary trial Id

-

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

##### Street address

Ahwaz Jundishapur University of Medical Sciences, Golestan road, Ahwaz, Khuzestan

##### City

Ahwaz

##### Postal code

6135715794

#### Approval date

2015-09-23, 1394/07/01

## Ethics committee reference number

IR.AJUMS.REC.1394.338

## Health conditions studied

### 1

#### Description of health condition studied

Pain

#### ICD-10 code

M79.6

#### ICD-10 code description

Pain in limb

## Primary outcomes

### 1

#### Description

Pain severity

#### Timepoint

Before intervention and 5, 10, 15, 20, 25 and 30 minutes after intervention

#### Method of measurement

Visual analog scale

## Secondary outcomes

### 1

#### Description

Vital sign

#### Timepoint

Before intervention and 5, 10, 15, 20, 25 and 30 minutes after intervention

#### Method of measurement

Cardiopulmonary monitoring

## Intervention groups

### 1

#### Description

Patients in intranasal ketamine hydrochloride group will receive 1 mg/kg ketamine hydrochloride of 10 ml solution (which put in sterile nasal drop bottle) via inhalation.

#### Category

Treatment - Drugs

### 2

#### Description

Patients in intravenous morphine sulfate group will receive 0.1 mg/kg morphine sulfate via intravenous

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ahvaz Imam Khomeini hospital

**Full name of responsible person**

Arash Forouzan

**Street address**

Emam Khomeini hospital, Ahvaz, Khuzestan

**City**

Ahvaz

### 2

#### Recruitment center

**Name of recruitment center**

Ahvaz Golestan hospital

**Full name of responsible person**

Somayyeh Gharibi

**Street address**

Golestan hospital, Golestan road, Ahvaz, Khuzestan

**City**

Ahvaz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**

Nader Saki

**Street address**

Ahvaz Jundishapur University of Medical Sciences, Golestan road, Ahvaz, Khuzestan

**City**

Ahvaz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Ahvaz Imam Khomeini hospital

**Full name of responsible person**

Somayyeh Gharibi

**Position**

Resident of emergency medicine

**Other areas of specialty/work****Street address**

Imam Khomeini hospital, Azadegan road, Ahvaz, Khuzestan

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6193673166

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Dr.s.gharibi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ahvaz Imam Khomeini hospital

**Full name of responsible person**

Arash Forouzan

**Position**

Assistant professor of emergency medicine

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**

Arsalan Tahmasbi

**Position**

Medical student

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*